Systematic searches in the electronic databases MEDLINE, EMBASE and The Cochrane library were conducted and 53 online databases (including HTA agency websites, international ministries of health, and clinical trials. gov) were hand searched for clinical guidelines in the treatment of MO caused by RVO. **RESULTS:** Fifteen documents on treatment pathways or guidance used internationally were identified from the hand searches. No papers or abstracts were found from the electronic database searches. There were considerable between-jurisdiction differences in the guidance for the management of MO caused by RVO. These differences were consolidated to produce two amalgamated treatment pathways. In total, eight treatment positions for interventions in the treatment of RVO subtypes were identified. For one of the identified positions – treatment of ischaemic branch RVO – no licensed treatment currently exists. **CONCLUSIONS:** The described systematic methodology for the construction of treatment pathways may be used by manufacturers in early drug development decisions to identify unmet clinical needs, understand which treatment positioning may provide the most value, and identify future treatment comparators in the same indication. Guidelines to inform such commercial strategies may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. Between jurisdiction guideline nuances also need to be taken into account when considering the target market for an intervention in development.

PSS59

OPHTHALMOLOGY: THERAPY TRENDS IN EUROPE BASED ON CLINICAL TRIAL REGISTRY DATA

Gupta A, Mukherjee B, Mahal SS, Mathews A
Novartis Healthcare Pvt Ltd, Hyderabad, India

OBJECTIVES: Ophthalmology pharmaceutical market is growing worldwide due to rising aging population, new delivery technologies and changing lifestyle. However, challenges like patent expiry of major brands and lack of awareness still persists. Therefore, it is important to be aware of the upcoming treatment options, changing patients' needs and requirement of cost effective therapies. This analysis provides an overview of the recent trends and future scenario in Ophthalmology market. **METHODS:** Pharmaceutical companies sponsored clinical trials initiated from January 2011 to April 2014 in Glaucoma, Age-related Macular Degeneration (AMD), Diabetic Retinopathy (DR) / Diabetic Macular Edema (DME), Dry eye syndrome (DES) and Retinal vein occlusion (RVO) have been considered. Only Phase I - III trials listed on public registries have been considered. **RESULTS:** The data showed that >30% of the trials are being conducted on Glaucoma in USA, Europe, Asia and Australia. This is followed by AMD (24%), DR/DME (21%), DES (17%) and RVO (7%). Also, >50% ophthalmological trials are being conducted in USA; followed by Europe (~25%) and Asia (~20%). In Europe, 71 trials have been conducted on 48 molecules, of which 69% are chemical entities, 19% are biologicals and >10% are entities like RNAi (oligonucleotide, aptamers), DARPin. Eye drops (46%) and intravitreal injections (37%) are the key topical and parenteral formulations, respectively. 10% of the trials have been conducted on oral formulations. In Europe, EU5 countries comprise of 43% of the trials and Germany has maximum 37 trials. Novartis has conducted trials in maximum 30 countries, followed by Santen (19), Pfizer (15) and Allergan (13) in Europe. **CONCLUSIONS:** Based on the analysis, currently, Glaucoma, AMD and DR/DME are the major focus of the companies in ophthalmology. Though, biologicals and RNAi are being tested routinely, chemical entities are foremost modalities. Similarly, eye drops remain as preferred method of delivery with respect to other newer delivery techniques.

RESEARCH POSTER PRESENTATIONS - SESSION V

DISEASE-SPECIFIC STUDIES
CANCER – Clinical Outcomes Studies

PCN1

TREATMENT PATTERNS AND HEALTH OUTCOMES AMONG PATIENTS WITH RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER IN THE UNITED STATES AND WESTERN EUROPE

Gianoukakis AG[1], Flores NM[2], Pelletier CL[3], DiBonaventura M[2], Forsythe A[3], Wolfe G[2], Rege J[3], Taylor MH[4]
[1]*University of California, Los Angeles, Torrance, CA, USA,* [2]*Kantar Health, New York, NY, USA,* [3]*Eisai Inc, Woodcliff Lake, NJ, USA,* [4]*Oregon Health & Science University, Division of Hematology & Medical Oncology, Portland, OR, USA*

OBJECTIVES: Most patients with differentiated thyroid cancer (DTC) have an excellent prognosis after receiving standard treatment, consisting of surgery and often adjuvant radioactive iodine (RAI). However, a subgroup of patients prove to have progressive DTC which is refractory to RAI (RRDTC). Treatment options for RRDTC are limited. This study investigated the treatment patterns and health care resource utilization of patients with RRDTC. **METHODS:** Data were collected by performing a retrospective chart review study in the US and 5EU (France, Germany, Italy, Spain, UK) with physicians recruited from an online panel. Physicians provided clinical information on 1 to 4 of their RRDTC patients in an online survey. Demographics, disease history, treatment information, and health care resource were included and reported descriptively. Health care resource use was compared across treatment classes using general linear models. **RESULTS:** 231 physicians participated and provided a total of 700 patient charts (44.1% of charts were from the US and 11-12% from each 5EU country). 45.0% of patients were male with a mean age at diagnosis of 55.1 years [SD=12.4]. 52.0% of patients were treated with systemic treatment (e.g., 16.9% tyrosine kinase inhibitors [TKIs] only; 13.3% chemotherapy only). The remaining 48.0% were either in a watch and wait ("WW") period (20.1%) or were managed with non-systemic palliative therapies (27.9%; eg, external beam radiation). Overall, patients averaged 15.87 days hospitalized per year (due to disease related complications or side effects). Although not statistically significant (p>.05), a trend toward more days hospitalized from disease-associated complications was observed for patients managed with WW (Mean=9.21, respectively) and non-systemic treatment (Mean=8.27) than patients treated with chemotherapy (Mean=7.25) or TKIs (Mean=8.22). **CONCLUSIONS:** Among patients diagnosed with RRDTC, watch and wait and non-systemic treatment options remain common. A large direct cost burden may be observed given the frequent and long hospital stays.

PCN2

APPROVING DRUGS BASED ON EARLY STAGE DATA - HOW PHASE II TRIAL DATA CORRELATES WITH PHASE III OUTCOMES. CASE STUDY: NSCLC

Macaulay R, Tan H
HERON Commercialization, London, UK

OBJECTIVES: There is increasing pressure on regulators from patients, physicians and industry for earlier access to pharmaceuticals for serious diseases. In reaction, in March 2014 the European Medicines Agency (EMA) announced it was piloting adaptive licensing, and the Medicines and Health care products Regulatory Agency (MHRA) unveiled their Early Access to Medicines Scheme. Nevertheless, there are questions over how, and if, Phase II trial benefits can be predictive of clinical advantages in Phase III studies, which this research aims to address. **METHODS:** Phase III data of any Non-Small Cell Lung Cancer (NSCLC) oncologic appraised by the EMA, or that had failed Phase III clinical trials, since 2002 was extracted along with its corresponding Phase II data. Statistical tests were conducted using Pearson's coefficient correlation. **RESULTS:** 12 oncologics were identified with both Phase II and III readouts, 6 of which met their Phase III trial primary endpoint. Overall Response Rates (ORRs) reported in Phase II trials varied from 0%-61% (mean 24%). 4/4 (100%) drugs with Phase II ORRs >30% met their primary endpoint vs. only 2/8 (25%) with ORRs ≤30%. Phase II ORRs were strongly correlated with Phase III Progression-Free Survival (PFS) (r^2=0.864, p<0.0005) and Overall Survival (OS) outcomes (r^2=0.858, p<0.001). Nevertheless, 5/6 drugs that failed their Phase III primary endpoints had comparative Phase II data indicating benefits versus these same comparators, most notably onartuzumab, whose Phase III trial was terminated early due to lack of efficacy, despite demonstrating significant OS benefits of 8.8 months in Phase II. **CONCLUSIONS:** In NSCLC, Phase II ORRs can be strongly predictive of the magnitude of PFS and OS readouts in Phase III trials. However, comparative advantages in Phase II trials seem to be poorly predictive of OS benefits in Phase III studies, raising questions over the appropriateness of approving drugs on early stage comparative data.

PCN4

CERVICAL HUMAN PAPILLOMA VIRUS (HPV) DNA PRIMARY SCREENING TEST RESULTS OF THE EXPERIENCE OF A REGIONAL LABORATORY IN CENTRAL ITALY

Passamonti BU[1], Bulletti S[1], Gustinucci D[1], Martinelli N[1], D'Amico MR[1], Spita N[1], Malaspina M[1], Carlani A[1], DI Dato E[1], Galeazzi P[1], Tintori B[1], D'angelo V[1], Calvi C[2]
[1]*Centro Unico di Screening Regione Umbria, PERUGIA, Italy,* [2]*ROCHE DIAGNOSTICS, MONZA, Italy*

OBJECTIVES: To investigate feasibility and effectiveness of a cervical screening program with DNA tests as preliminary assay versus usual cytology protocols in Umbria Region. **METHODS:** A large cohort of 35-64 aged women afferent to the unique regional laboratory was considered. The usual algorithm with cervical cytology as primary test was followed in January 2008–June 2010, whereas in August 2010–October 2011 high-risk human papillomavirus (HR-HPV) DNA test was used as primary screening. The cohorts were compared in terms of acceptance rate of invitation, cytological results, molecular results including HPV genotype, detection rate of histological lesions. **RESULTS:** A total of 31,228 women were invited: 21,249 were suggested to undergo classical cervical cytology screening, 9,979 HR-HPV DNA test as primary screening. A similar rate of adhesion (56.6% vs. 56.5%) was observed. Age-related differences were evidenced, with younger women (35-49) more prone to accept the invitation to HR-HPV DNA testing rather than usual cytology screening (61.6% vs. 55.5%; p<0.0001); analogously, uninvited younger women spontaneously requesting cervical screening were more prone to specifically request molecular than classical cytological testing (24.8% vs. 10.8%; p<0.0001). Among the 6,272 HR-HPV DNA testing women, 396 (6.4%) were positive, and, among them, 141 (36%) featured an altered cytology. All patients with altered cytology were suggested to undergo colposcopy and 106 out of 141 (75.1%) answered to the invitation. Among them, 89 (84%) featured abnormal histology with 48 (45.3%) CIN1 and 41 (38.7%) CIN2. If comparing the CIN2 detection rate within the two studied periods, it was almost doubled using the HR-HPV DNA than pap test as primary assay (0.64% vs. 0.37%; p=0.005). Finally, the implementation of the DNA test screening program did not increase total costs. **CONCLUSIONS:** Although with some limits, the introduction of HR-HPV DNA primary testing resulted feasible and effective, significantly increasing detection of severe lesions.

PCN5

COMPARATIVE EFFECTIVENESS OF TREATMENTS FOR RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA (R/R MCL), USING MATCHING ADJUSTED INDIRECT COMPARISON

Tongbram V[1], Sengupta N[2], Gaudig M[3], Sidhu M[1], Exuzides A[4], Colby C[4], Sanden SV[5], McGovern A[1]
[1]*ICON Plc, Morristown, NJ, USA,* [2]*Janssen Pharmaceuticals, Inc, Raritan, NJ, USA,* [3]*Janssen Pharmaceuticals, Inc, Neuss, Germany,* [4]*ICON Plc, San Francisco, CA, USA,* [5]*Janssen Pharmaceuticals, Inc., Beerse, Belgium*

OBJECTIVES: Prognosis for relapsed or refractory (R/R) MCL patients with existing treatments is poor; most patients progress within ~4 months. Ibrutinib, an oral once daily Bruton's tyrosine kinase inhibitor showed durable single agent activity with good response rate in 111 R/R MCL patients and a median progression free survival (PFS) of 13.9 months. Ibrutinib received breakthrough designation and United States Food and Drugs Administration approval for use in MCL patients who received at least one prior therapy (R/R MCL). This indirect analysis aims to compare the efficacy